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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,133	Applicant(s) FREI ET AL.	
	Examiner Christopher A. Flory	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/28/04, 6/14/04, and 11/23/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The reference to US patent 4,692,147 in the specification is not considered to be part of a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
2. The references to the journal article "Seizure Recognition and Analysis" by J. Gotman is not considered to be part of a proper information disclosure statement. 37 CFR 1.98(b) requires that each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, *date*, and place of publication. The Gotman citation lacks the date requirement, and it has therefore not been considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 501 (Fig. 5); 1009, 1027 (Fig. 10); 1109, 1117, 1121 (Fig. 11); 22, 24 (Fig. 12); 1425, 1430, 1435 (Fig. 14); 1501, 1519 (Fig. 15); 1600 (Fig. 16); 1191 (Fig. 19); 2001 (Fig. 20). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid

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abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate wire(?) in Fig. 12 as well as catheter and skull(?) in Fig. 13. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 1 is objected to because of the following informalities: there is a typographical error in the fourth clause reading "from the first electrode **to and** a selected signal through...". Appropriate correction is required.
7. Claim 10 is objected to because of the following informalities: there is a typographical error reading "The medical device system **of claim of claim 5**". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 1, 7, 14, 19, 22-23, and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claim 1 recites the limitation "the detection module" in the fourth clause and "the stimulation module" in the fifth clause of the claim. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests that the claim language be changed to read either –a detection module— and –a stimulation module—; or –the detection *unit*— and –the stimulation *unit*— in order to distinctly claim the invention.

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11. In claims 1, 7, 14 and 19, it is unclear whether "disconnecting" the first or selected electrode from the first or selected amplifier refers to a mechanical switch that physically disconnects the circuitry (hardware blanking), software blanking means, or an alternate means such as shorting the first or selected electrode to the sensing reference electrode. The examiner has interpreted the "disconnecting" in its broadest reasonable interpretation as being any one of the three above listed methods.

12. In claim 22, the phrase "corresponding output ratio" is unclear as to what elements are in the ratio and what element of the invention it corresponds to.

13. Claim 23 recites the limitation "the second electrode" in the final line of the claim. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests that the claim language be changed to read —a selected electrode—in order to distinctly claim the invention.

14. In claims 38-43, it is unclear if the medium, the instructions or both are being claimed. Apparatus claims cannot solely claim computer instructions. It is suggested to first positively recite the tangible computer medium before additionally claiming the instructions.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1-23 and 28-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (US Patent 6,016,449).

Regarding claims 1-11, Fischell et al. shows a medical device system that provides treatment therapy for a nervous system disorder (**title**) comprising a first electrode (Fig. 2, electrode 15A) and a selected electrode (any of electrodes 15A-N) with a first and selected amplifier (Fig. 3, amplifiers 32A-N) connecting the first and selected input ports (wires 17A-N) respectively; a stimulation unit that applies a stimulation signal in response to a detection cluster being indicative of a seizure (stimulation sub-system 40; column 2, line 52 through column 3, line 3); and a detection unit (event detection sub-system 30) comprising a processing module (central processor 51) for analyzing the first and selected signals and generating the responsive stimulation signal from the first electrode; a first blanking module for disconnecting the first electrode during the application of a stimulation signal and a second blanking module which determines whether to process the first or selected response signals (column 12, lines 10-44; column 14, lines 11-15); wherein the duration of the first and second blanking intervals are approximately equal (column 13, lines 51-55; column 14, lines 11-16; and column 22, lines 4-33); further comprising a timing module (real time clock 91; column 13, lines 24-35); and a data storage unit (memory 55) for storing data

representing the first and selected signals (column 4, lines 45-56; column 18, lines 42-63; step 5 of the method outlined in column 13).

Regarding claim 4, Fischell discloses a single signal is sent from the stimulation sub-system during brain stimulation to shut down amplifiers 131A-N (i.e. blanks the first and selected signals) to avoid amplifier overload or mistakenly identify a stimulation signal as a neurological signal (column 24, lines 9-13; Fig. 12). Because only one signal is used to blank all electrodes A-N, it is understood that the blanking periods for any combination of first and selected electrodes must necessarily be equal

Further regarding disconnecting the first and selected electrodes as addressed claims 7, 14 and 19, Fischell et al. discloses a software blanking means in which the event detection subsystem is temporarily disabled during stimulation to prevent creating an undesired input signal into the event-detection subsystem (column 12, lines 39-44 and column 14, lines 11-15). Fischell et al. also discloses a hardware blanking means in which the first and selected electrode could be shorted by switching circuitry in the stimulation sub-system in order to prevent overloading of the amplifiers (column 12, lines 10-15 and column 14, lines 11-15).

Regarding claims 12-37 and 44, Fischell et al. discloses a method for providing treatment of epileptic seizures comprising the step of receiving and amplifying a first and selected signal (or several selected signals), analyzing the amplified signals, delivering treatment in response to that analysis, and blanking both signals during an essentially equal blanking time interval, wherein blanking comprises disconnecting the first and selected electrodes from the first and selected amplifiers at the time that a

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treatment stimulation pulse is being delivered (column 13, line 36 through column 14, line 16); wherein the first and selected amplifiers are connected to a constant voltage source (column 5, lines 50-60 and column 12, lines 45-64); and further comprising the step of storing data representative of the first and selected signals (column 18, line 42 through column 19, line 2; step 5 of the method in column 13).

Regarding claim 18, Fischell et al. discloses that the detection sub-system be temporarily disabled "when stimulation is imminent so that the stimulation signals are not inadvertently interpreted as a neurological event by the event detection system" (column 12, lines 31-44; step 4 of the method outlined in column 13). The examiner takes this disclosure to be analogous to the claim of the instant application because a stimulation signal misinterpreted as a neurological event is commonly referred to as an "artifact" by those skilled in the art. Therefore blanking the selected signal in response to an artifact generated by the first stimulation pulse is simply a different phraseology for saying the same thing—that the detection sub-system (i.e. selected electrode) be temporarily disabled to avoid misinterpretation of stimulation signals as neurological events (i.e. artifacts).

Regarding claim 22, if "a corresponding output ratio" is in reference to the stimulation signals delivered by the system, Fischell et al. discloses that the stimulation signals may be pure d-c voltages, which would imply a constant ratio (column 22, lines 37-52). If the "corresponding output ratio" is in reference to the output of the detection sub-system (selected electrode) during the blanking period resulting from stimulation delivery, then Fischell et al. discloses that the detection sub-system is physically

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blanked during stimulation delivery, which would result in a constant zero output (i.e. constant ratio) during the second blanking time interval.

Regarding claims 23 and 28, Fischell et al. discloses the use of a multiplicity of electrodes to calculate—by means of time delays arising from the inter-electrode distances of a specific geometric configuration—sense and specifically locate the source of a desired neurological event or artifact and then deliver therapy (i.e. stimulation pulses) to a specific desired location (column 2, line 52 through column 3, line 25; column 16, line 54 through column 17, line 55).

Regarding claims 38-43, central processor 51 and memory 55 (Fig. 2) as disclosed in Fischell et al. to consist of either RAM or flash memory (column 22, lines 1-5) comprises a computer-readable capable of and intended for performing the methods outlined in the instant application.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.

Regarding claims 24-27, Fischell et al. discloses the method substantially as claimed, including an event detection means based on detecting specific aspects of the waveform of either time or frequency domain outputs of the detection sub-system including pulse width, first derivative, or waveform shape (column 20, lines 34-40). Fischell does not explicitly disclose the step of using a perturbation of the selected signal, flat-lining of the selected signal, measuring an associated impedance or determining the saturation of the selected electrode resulting from an artifact in the first electrode to determine the second blanking time interval. However, it is well-known to one skilled in the art that a perturbation of the selected signal can be calculated from an uncharacteristic first derivative (changing slope) of the time-domain waveform; that excessive flat-lining and saturation can be calculated in either the time or frequency domain; and that impedance is a commonly identifiable characteristic of a frequency-domain waveform (a change of impedance results in a phase shift, e.g. of the Bode plot characterizing the monitored signal).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use one of these calculations as a means for determining the

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occurrence of an artifact on a selected signal in order to determine the appropriate length of the blanking time interval for that selected electrode.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

GEORGE R. EVANISKO
PRIMARY EXAMINER
4/20/16